

## THE CLAIMS

What is claimed is:

- 5           1.       A propellant free buccal spray composition for transmucosal administration  
of a pharmacologically active compound comprising:  
                  an active compound in an amount of between 0.001 and 60 percent by  
weight of the total composition selected from the group consisting of anti-opioid agents,  
anti-migraine agents, pain control agents, anesthetics, and mixtures thereof; and  
10               a polar solvent in an amount between 30 and 99 percent by weight of the  
total composition.
2.       The composition of claim 1, further comprising a flavoring agent in an  
amount of between 0.1 and 10 percent by weight of the total composition.
- 15           3.       The composition of claim 2, wherein the polar solvent is present in an  
amount between 37 and 98 percent by weight of the total composition, the active compound  
is present in an amount between 0.005 and 55 percent by weight of the total composition,  
and the flavoring agent is present in an amount between 0.5 and 8 percent by weight of the  
20           total composition.
4.       The composition of claim 3, wherein the polar solvent is present in an  
amount between 60 and 97 percent by weight of the total composition, the active compound  
is present in an amount between 0.01 and 40 percent by weight of the total composition, and  
25           the flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the  
total composition.
5.       The composition of claim 1, wherein the polar solvent is selected from the  
group consisting of polyethylene glycols having a molecular weight between 400 and 1000,  
30           C<sub>2</sub> to C<sub>8</sub> mono- and poly-alcohols, and C<sub>7</sub> to C<sub>18</sub> alcohols of linear or branched  
configuration.

6. The composition of claim 1, wherein the polar solvent comprises aqueous polyethylene glycol.

5 7. The composition of claim 1, wherein the polar solvent comprises aqueous ethanol.

8. The composition of claim 1, wherein the active compound is an anti-opioid agent selected from the group consisting of naloxone, nalmeferone, naltrexone, cholecystokinin, nociceptin, neuropeptide FF, oxytocin, vasopressin, and mixtures thereof.

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9. The composition of claim 1, wherein the active compound is an anti-migraine agent selected from the group consisting of frovatriptan, zolmitriptan, rizatriptan, almotriptan, eletriptan, naratriptan, almotriptan, ergotamine, diethylergotamine, sumatriptan, and mixtures thereof.

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10. The composition of claim 1, wherein the active compound is a pain control agent selected from the group consisting of non-steroidal anti-inflammatory drugs, alfentanil, butorphanol, codeine, dezocine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, propoxyphene, pentazocine, sufentanil, tramadol, and mixtures thereof.

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11. The composition of claim 1, wherein the active compound is an anesthetic selected from the group consisting of benzonatate, bupivacaine, desflurane, enflurane, isoflurane, levobupivacaine, lidocaine, mepivacaine, prilocaine, propofol, rapacuronium bromide, ropivacaine, sevoflurane, ketamine, and mixtures thereof.

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12. The composition of claim 2, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

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13. A method of administering a pharmacologically active compound to a mammal comprising spraying the oral mucosa of the mammal with the composition of claim 1.

14. The method of claim 13, wherein the amount of the spray is predetermined.

15. A buccal spray composition for transmucosal administration of a pharmacologically active compound comprising:

5 an active compound in an amount of between 0.1 and 25 percent by weight of the total composition selected from the group consisting of anti-opioid agents, anti-migraine agents, pain control agents, anesthetics, and mixtures thereof;

a polar solvent in an amount between 10 and 97 percent by weight of the total composition; and

10 a propellant in an amount between 2 and 10 percent by weight of the total composition, wherein said propellant is a C<sub>3</sub> to C<sub>8</sub> hydrocarbon of linear or branched configuration.

16. The composition of claim 15, further comprising a flavoring agent in an amount between 0.05 and 10 percent by weight of the total composition.

17. The composition of claim 16, wherein the polar solvent is present in an amount between 20 and 97 percent by weight of the total composition, the active compound is present in an amount between 0.1 and 15 percent by weight of the total composition, the propellant is present in an amount between 2 and 5 percent by weight of the composition, and the flavoring agent is present in an amount between 0.1 and 5 percent by weight of the total composition.

18. The composition of claim 17, wherein the polar solvent is present in an amount between 25 and 97 percent by weight of the total composition, the active compound is present in an amount between 0.2 and 25 percent by weight of the total composition, the propellant is present in an amount between 2 and 4 percent by weight of the composition, and flavoring agent is present in an amount between 0.1 and 2.5 percent by weight of the total composition.

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19. The composition of claim 15, wherein the polar solvent is selected from the group consisting of polyethyleneglycols having a molecular weight between 400 and 1000,

C<sub>2</sub> to C<sub>8</sub> mono- and poly-alcohols, and C<sub>7</sub> to C<sub>18</sub> alcohols of linear or branched configuration.

20. The composition of claim 19, wherein the polar solvent comprises aqueous polyethylene glycol.

21. The composition of claim 19, wherein the polar solvent comprises aqueous ethanol.

22. The composition of claim 15, wherein the active compound is an anti-opioid agent selected from the group consisting of naloxone, nalmefene, naltrexone, cholecystikinin, nociceptin, neuropeptide FF, oxytocin, vasopressin, and mixtures thereof.

23. The composition of claim 15, wherein the active compound is an anti-migraine agent selected from the group consisting of frovatriptan, zolmitriptan, rizatriptan, almotriptan, eletriptan, naratriptan, almotriptan, ergotamine, diethylergotamine, sumatriptan, and mixtures thereof.

24. The composition of claim 15, wherein the active compound is a pain control agent selected from the group consisting of non-steroidal anti-inflammatory drugs, alfentanil, butorphanol, codeine, dezocine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, propoxyphene, pentazocine, sufentanil, tramadol, and mixtures thereof.

25. The composition of claim 15, wherein the active compound is an anesthetic selected from the group consisting of benzonatate, bupivacaine, desflurane, enflurane, isoflurane, levobupivacaine, lidocaine, mepivacaine, prilocaine, propofol, rapacuronium bromide, ropivacaine, sevoflurane, ketamine, and mixtures thereof.

26. The composition of claim 16, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

27. The composition of claim 15, wherein the propellant is selected from the group consisting of propane, *N*-butane, *iso*-butane, *N*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

5 28. A method of administering a pharmacologically active compound to a mammal comprising spraying the oral mucosa of the mammal with the composition of claim 15.

29. The method of claim 28, wherein the amount of the spray is predetermined.

10 30. A propellant free buccal spray composition for transmucosal administration of a pharmacologically active compound comprising:

an active compound in an amount between 0.005 and 55 percent by weight of the total composition selected from the group consisting of anti-opioid agents, anti-migraine agents, pain control agents, anesthetics, and mixtures thereof; and

15 a non-polar solvent in an amount between 30 and 99 percent by weight of the total composition.

20 31. The composition of claim 30, further comprising a flavoring agent in an amount between 0.1 and 10 percent by weight of the total composition.

25 32. The composition of claim 30, wherein the active compound is an anti-opioid agent selected from the group consisting of naloxone, nalmeferene, naltrexone, cholecystokinin, nociceptin, neuropeptide FF, oxytocin, vasopressin, and mixtures thereof.

33. The composition of claim 30, wherein the active compound is an anti-migraine agent selected from the group consisting of frovatriptan, zolmitriptan, rizatriptan, almotriptan, eletriptan, naratriptan, almotriptan, ergotamine, diethylergotamine, sumatriptan, and mixtures thereof.

30 34. The composition of claim 30, wherein the active compound is a pain control agent selected from the group consisting of non-steroidal anti-inflammatory drugs, alfentanil, butorphanol, codeine, dezocine, fentanyl, hydrocodone, hydromorphone,

levorphanol, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, propoxyphene, pentazocine, sufentanil, tramadol, and mixtures thereof.

5           35.     The composition of claim 30, wherein the active compound is an anesthetic selected from the group consisting of benzonatate, bupivacaine, desflurane, enflurane, isoflurane, levobupivacaine, lidocaine, mepivacaine, prilocaine, propofol, rapacuronium bromide, ropivacaine, sevoflurane, ketamine, and mixtures thereof.

10           36.     The composition of claim 31, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

15           37.     The composition of claim 30, wherein the solvent is selected from the group consisting of ( $C_2$ - $C_{24}$ ) fatty acid ( $C_2$ - $C_6$ ) esters,  $C_7$ - $C_{18}$  hydrocarbons of linear or branched configuration,  $C_2$ - $C_6$  alkanoyl esters, and triglycerides of  $C_2$ - $C_6$  carboxylic acids.

          38.     The composition of claim 37, wherein the solvent is miglyol.

20           39.     A method of administering a pharmacologically active compound to a mammal comprising spraying the oral mucosa of the mammal with the composition of claim 30.

          40.     The method of claim 39, wherein the amount of the spray is predetermined.

25           41.     A buccal spray composition for transmucosal administration of a pharmacologically active compound comprising:

                  an active compound in an amount between 0.05 and 50 percent by weight of the total composition selected from the group consisting of anti-opioid agents, anti-migraine agents, pain control agents, anesthetics, and mixtures thereof; and

30                   a non-polar solvent in an amount between 19 and 85 percent by weight of the total composition; and

a propellant in an amount between 5 and 80 percent by weight of the total composition, wherein said propellant is a C<sub>3</sub> to C<sub>8</sub> hydrocarbon of linear or branched configuration.

5           42.     The composition of claim 41, further comprising a flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

          43.     The composition of claim 42, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil,  
10   fruit flavors, sweeteners, and mixtures thereof.

          44.     A buccal spray composition for transmucosal administration of a pharmacologically active compound comprising:  
                  an active compound in an amount between 0.01 and 40 percent by weight of  
15   the total composition selected from the group consisting of anti-opioid agents, anti-migraine agents, pain control agents, anesthetics, and mixtures thereof; and  
                  a non-polar solvent in an amount between 25 and 89 percent by weight of the total composition;  
                  a propellant in an amount between 10 and 70 percent by weight of the total  
20   composition, wherein said propellant is a C<sub>3</sub> to C<sub>8</sub> hydrocarbon of linear or branched configuration; and  
                  A flavoring agent is present in an amount between 1 and 8 percent by weight of the total composition.

25           45.     The composition of claim 44, wherein the propellant is present in an amount between 20 and 70 percent by weight of the total composition, the non-polar solvent is present in an amount between 25 and 75 percent by weight of the total composition, the active compound is present in an amount from between 0.25 and 35 percent by weight of the total composition, and the flavoring agent is present in an amount between 2 and 7.5  
30   percent by weight of the total composition.

46. The composition of claim 42, wherein the propellant is selected from the group consisting of propane, *n*-butane, *iso*-butane, *n*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

5 47. The composition of claim 46, wherein the propellant is *n*-butane or *iso*-butane and has a water content of not more than 0.2 percent and a concentration of oxidizing agents, reducing agents, Lewis acids, and Lewis bases of less than 0.1 percent.

10 48. The composition of claim 41, wherein the solvent is selected from the group consisting of (C<sub>2</sub>-C<sub>24</sub>) fatty acid (C<sub>2</sub>-C<sub>6</sub>) esters, C<sub>7</sub>-C<sub>18</sub> hydrocarbons of linear or branched configuration, C<sub>2</sub>-C<sub>6</sub> alkanoyl esters, and triglycerides of C<sub>2</sub>-C<sub>6</sub> carboxylic acids.

49. The composition of claim 48, wherein the solvent is miglyol.

15 50. The composition of claim 41, wherein the active compound is an anti-opioid agent selected from the group consisting of naloxone, nalmefene, naltrexone, cholecystokinin, nociceptin, neuropeptide FF, oxytocin, vasopressin, and mixtures thereof.

20 51. The composition of claim 41, wherein the active compound is an anti-migraine agent selected from the group consisting of frovatriptan, zolmitriptan, rizatriptan, almotriptan, eletriptan, naratriptan, almotriptan, ergotamine, diethylergotamine, sumatriptan, and mixtures thereof.

25 52. The composition of claim 41, wherein the active compound is a pain control agent selected from the group consisting of non-steroidal anti-inflammatory drugs, alfentanil, butorphanol, codeine, dezocine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, propoxyphene, pentazocine, sufentanil, tramadol, and mixtures thereof.

30 53. The composition of claim 41, wherein the active compound is an anesthetic selected from the group consisting of benzonatate, bupivacaine, desflurane, enflurane, isoflurane, levobupivacaine, lidocaine, mepivacaine, prilocaine, propofol, rapacuronium bromide, ropivacaine, sevoflurane, ketamine, and mixtures thereof.



54. A method of administering a pharmacologically active compound to a mammal comprising spraying the oral mucosa of the mammal with the composition of claim 41.

5 55. The method of claim 54, wherein the amount of the spray is predetermined.